REMARKS

Claims 1-69 are pending. Claims 1-4 and 9-69 are cancelled as being drawn to a non-elected invention. Claim 5 is amended to include the limitations of claim 6. Claim 6 is cancelled. New claims 70-72 have been added. Support for new claim 70 is found throughout the specification and in particular at page 18, line 30 through page 19, line 6. Support for new claim 71 is found throughout the specification and in particular at page 20, line 3 through page 22, line 9. Support for new claim 72 is found throughout the specification and in particular at page 20, lines 3 through 10.

Applicants submit that no new matter has been added as a result of this amendment.

Information Disclosure

In response to the Examiner's comments at page 2 of the Office Action, Applicants submit herewith a Supplemental Information Disclosure Statement that includes the references cited on pages 88-92 of the instant application not previously cited in the Information Disclosure filed on August 23, 2004.

Specification

Applicants have amended the specification to address the Examiner's comments at page 3 of the Office Action.

Drawings

Attached are substitute Figures 7-9, 13 and 14-17 that have been amended in accordance with the Examiner's comments at pages 3 through 4 of the Office Action.

Rejection of Claims 5-8 Under 35 U.S.C. §102(b)

Claims 5-8 are rejected under 35 U.S.C. §102(b) for alleged lack of novelty over Van Ooigen et al. (U.S. 6,022,846).

The Examiner states at pages 4-5 of the Office Action that "Van Ooijen et al. disclose a stable transgenic tobacco plant comprising expression of a heterologous protein phytase, wherein phytase **inherently** has the properties of an antigen. The reference further discloses that said transgenic material is milled or ground to produce a stable feed meal for animals."

Applicants respectfully traverse the rejection.

Applicants submit that the Examiner must provide rationale or evidence tending to show inherency to properly make a rejection under 35 U.S.C. 102 when the prior art is silent as to an inherent characteristic (MPEP §2112).

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) ...; *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. **Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**' " " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (Emphasis) (MPEP §2112, citations omitted).

The instant claims refer to "a stable dry homogenate of a transgenic plant expressing a heterologous protein, wherein the **heterologous protein comprising an antigen or an antibody**. (Emphasis added) The instant specification describes numerous uses of the claimed stable dry homogenate of a transgenic plant expressing a heterologous protein as a vaccine or antibody, for example, for use in immunocontraception (see for example page 20, lines 3 through 10).

Applicants submit that the Examiner has not demonstrated that the phytate described in the Van Ooijen et al. reference teaches that phytate presented as a food or food additive functions as an antibody and or an antigen. That is, the Examiner has failed to present extrinsic evidence that "make[s] clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. According to case law, the mere possibility that phytate presented to an animal may induce an immune response (that is an antibody response) or may function as an antibody is not sufficient to establish inherency.

In view of the above, Applicants submit that the Van Ooigen et al. reference does not teach or suggest "a stable dry homogenate of a transgenic plant expressing a heterologous protein comprising an antigen or an antibody, prepared by a method comprising: a. obtaining either intact or partitioned transgenic plant material; b. dehydrating said transgenic plant material; c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step, thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein" as required by amended claim 5.

Applicants have added new claim 70 that recites "the stable dry homogenate of claim 5, further comprising an excipient." "Excipient" is defined in the instant application at page 19, lines 3-6 as "extraneous material added at any stage of processing. For example. Excipients may be added when partitioning the transgenic plant material, or added during dehydration, or added upon mixing pre-or post dehydration. Suitable excipients include but are not limited to, adjuvants, buffers, sugars, antioxidants, stabilizers, or antigenic powders."

Applicants submit that the Van Ooigen et al. reference does not teach or suggest "a stable dry homogenate of a transgenic plant expressing a heterologous protein comprising an antigen or an antibody, prepared by a method comprising: a. obtaining either intact or partitioned transgenic plant material; b. dehydrating said transgenic plant material; c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step, thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein, further comprising an excipient" as required by instant claim 70.

Applicants have also added new claim 71 that recites "the stable dry homogenate of claim 5, wherein administration of said homogenate to an animal induces an immune response." An "immune response" is defined in the instant specification at page 20, lines 11 through 12 as "a response made by the immune system of an organism to a substance, which includes but is not limited to foreign or self proteins."

Applicants submit that the Van Ooigen et al. reference does not teach or suggest "a stable dry homogenate of a transgenic plant expressing a heterologous protein comprising an antigen or an antibody, prepared by a method comprising: a. obtaining either intact or partitioned transgenic plant material; b. dehydrating said transgenic plant material; c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step, thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein, wherein administration of said homogenate to an animal induces an immune response" as required by instant claim 70.

Applicants have also added new claim 72 that recites "the stable dry homogenate of claim 5, wherein administration of said homogenate to an animal induces immunocontraception. "Immunocontraception" is defined in the instant specification at page 20, lines 3 through 10 as "temporary, reversible contraception, and also to permanent non-reversible contraception, or sterilization, resulting from an immune response to a contraceptive protein. As used herein, "immunocontraception" is deemed to be "effective" if the average number of offspring per breeding cycle produced by an animal subjected to "immunocontraception" is reduced by at least 60%, 70%, 80%, 90% and even up to 100% for animal species which produce an average litter size of three or more offspring. For animal species which produce an average litter of less than 3 offspring, "effective" immunocontraception would result in a reduction in litter size by at least 50%, and up to 100%."

Applicants submit that the Van Ooigen et al. reference does not teach or suggest "a stable dry homogenate of a transgenic plant expressing a heterologous protein comprising an antigen or an antibofy, prepared by a method comprising: a. obtaining either intact or partitioned transgenic plant material; b. dehydrating said transgenic plant material; c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step, thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein, wherein administration of said homogenate to an animal induces immunocontraception" as required by instant claim 72.

In view of the above, Applicants submit that all claims are novel in view of the Van Ooigen et al. reference.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Respectfully submitted,

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By

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APPENDIX 1